P.01/20



Health Santé Canada Canada

Part II: 19 pages + this one.



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CONTINUING ASSESSMENT DIVISION / DIVISION DE L'ÉVALUATION CONTINUE BUREAU OF DRUG SURVEILLANCE / BUREAU DE LA SURVEILLANCE DES MÉDICAMENTS FINANCE BUILDING / ÉDIFICE FINANCE

> FIRST FLOOR / 1er ÉTAGE OTTAWA (ONTARIO) K1A 1B9

ADDRESS LOCATOR -0201C1 - INDICE DE L'ADRESSE FAX: (613) 957-0335

TO/À:

Robert Seidman

FAX: 1(818) 712-6482 TEL: (818) 610-4817

DATE: April 13, 1999

NUMBER OF PAGES TO FOLLOW: 61 NOMBRE DE PAGES À SUTVRE:

MESSAGE/MESSAGE:

Dear Mr. Seidman.

This is further to your fax dated December 16, 1998 requesting information on suspected adverse drug reactions (ADRs) associated with the use of cetirizine, fexofenadine and loratadine. We apologize for the delay.

A search of the national database was performed for all the suspected adverse reactions associated with these suspected drugs. The attached printouts outline the results. These printouts cover the time period since marketing until April 12, 1999. There may be reports which have been received by the program which are not yet entered into the database. Kindly direct your attention of all persons using these printouts to the following Caveat:

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Protection Branch is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Protection Branch scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization.

If you have any further questions, please do not hesitate to contact me.

APR.

Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0116264		em Organ C					60 Milligrams Daily re Reaction Term:	Unknown	
			Y SYSTEM DIS HOLE - GENER		RS	RHINITIS EFFICACY,	LACK OF		
0116365	BOI RES	em Organ C DY AS A W	HOLE - GENER SYSTEM DISC		I Day(s)	EFFICACY, SNEEZING		Recovered without sequelae	
0116366	ALLEGRA Syste BOI RES	em Organ C DY AS A W	HOLE - GENER SYSTEM DISC		Continuing on Drug	EFFICACY, SNEEZING I		Recovered without sequelae	,
D116367	ALLEGRA Syste VISI BOI RES	em Organ C ION DISOR DY AS A W SPIRATORY		ORDERS	12 Day(s)	Suspected WHO Advers EYE IRRITA EFFICACY, SNEEZING I RHINITIS	LACK OF	Not yet recovered	
	Ü						A		L 22 F F F F F F F F F F F F F F F F F F

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April 12, 1999

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0116368		27 Year(s)	Male					Not yet recovered	
	ALLEG	RA			12 Day(s)	Suspected	60 Milligrams Daily		
		ystem Organ Cla				WHO Advers	e Reaction Term.		
		ESPIRATORY				RHINITIS			
		ODY AS A WH			RS	EFFICACY,			
		ESPIRATORY		ORDERS		SNEEZING I			
		ISION DISORE				EYE IRRITA	TION		
	DECON	GEST NASAL	SPRAY			Concomitant			
0116375		-	Female					Not yet recovered	
	ALLEG	RA			l Day(s)	Suspected	1 Dosage form		
		ystem Organ Cla				7	e Reaction Term:		
		KIN AND APPI				PRURITUS			
		KIN AND APPI				ITCHING			
	В	ODY AS A WH	IOLE - GENEI	RAL DISORDE	RS	OEDEMA			
0116378		•	Male					Unknown	
	ALLEGI	R A				Suspected	60 Milligrams Daily		
	.S)	ystem Organ Clo	uss:				e Reaction Term:		Σ
		ISION DISORE				EYE IRRITA	TION		82РМ
• •	- R	ESPIRATORY	SYSTEM DIS	ORDERS	And the second second	RHINITIS			
	C	entr & Perif	PH NERVOUS	SYSTEM DISC	ORDERS	HEADACHE			. 51
0116379		•	Male					Unknown	
	ALLEGI	RA				Suspected			13,
	· S	ystem Organ Cla	ass:			WHO Advers	e Reaction Term:		0 0 70
	B	ODY AS A WH	IOLE - GENEI	RAL DISORDE	RS	EFFICACY,	LACK OF		ä
	R	ESPIRATORY	SYSTEM DIS	ORDERS		SNEEZING I	EXCESSIVE		
									<u>}</u>
									<u>+</u>
									۴

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Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Pexofenadine

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116380		27 Year(s)	Malc					Unknown
	ALLEGRA	X			Continuing on Drug	Suspected		
		em Organ Cl					e Reaction Term:	
				RAL DISORDE	RS	EFFICACY,		
			SYSTEM DIS	SORDERS		SNEEZING I	-	
		ION DISORI	DEKS			Other	ION ABNORMAL	
	REACTIN	E				Other		
0116381		43 Year(s)	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
•		em Organ Cl					e Reaction Term:	
	•		SYSTEM DIS		n a	RHINITIS	LACKOR	
	ВО	DY AS A WE	IOLE - GENE	RAL DISORDE	K2	EFFICACY,	LACK OF	
116382		13 Year(s)	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
		em Organ Cl		300000			e Reaction Term:	
			SYSTEM DIS	SORDERS		RHINITIS EYE IRRITATION EFFICACY, LACK OF		
		ION DISORI		RAL DISORDE	D C			
			SYSTEM DIS		NO TOTAL CONTRACTOR OF THE PROPERTY OF THE PRO	NASAL CON		and the second seco
0116383		40 Year(s)	Female					Recovered without sequelae
7110505	ALLEGRA				9 Day(s)	Suspected		
	Sys	em Organ Cl	ass:			WHO Advers	e Reaction Term:	
	RE	SPIRATORY	SYSTEM DIS	SORDERS		NASAL CON	NGESTION	
	VIS	ION DISORI	DERS				ION ABNORMAL	
		ION DISORI				EYE IRRITA		
			SYSTEM DIS			SNEEZING I		
				ERAL DISORDE	RS	EFFICACY,	LACK OF	
			SYSTEM DIS	SORDERS		RHINITIS Treatment		
J	FLONASI	i,				i real/neni		

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome		
0116384		18 Year(s)	Fentale					Recovered without sequela	e	
	ALLEGRA				9 Day(s)	Suspected				
		tem Organ Cl					e Reaction Term:			
		SION DISORI					ION ABNORMAL			
		SION DISORI				EYE IRRITA	TION			
			SYSTEM DIS			RHINITIS	lonamio) i			
			SYSTEM DIS			NASAL CON				
	FLONASE		SYSTEM DIS	OKDEKS		SNEEZING EXCESSIVE Treatment				
	FLONASE	ن 				A I CAMILLIN		·		
0116385		-	Female					Not yet recovered		
	ALLEGRA		_		1 Weck(s)	Suspected	120 Milligrams Daily			
		tem Organ Cl					e Reaction Term:			
		SION DISORI		-Annina		EYE IRRITA	TION			
			SYSTEM DIS	OKDERS RAL DISORDE	en c	RHINITIS EFFICACY, I	I YOU OF			
			' SYSTEM DIS		CN.	SNEEZING I				
		PERTENSIV		ONDERG		Concomitant	SVCENDIAT.			
0116386		37 Year(s)	Female					Not yet recovered	<u>-</u> -	
0110300	ALLEGR	A: ####	* *****	å ···	2 Day(s)	Suspected -	60 Milligrams Daily	Marine Spring Street	12:02PM	
		tem Organ Cl	lass:			WHO Adverse	e Reaction Term:	•	. 💆	
			SYSTEM DIS	ORDERS		NASAL CON	(GESTION	."	-	
			SYSTEM DIS			THROAT IR	RITATION		ď	
				RAL DISORDE	ERS	FEELING OF	F WARMTH		998. 13	
	ВО	DY AS A WI	HOLE - GENE	RAL DISORDE	ERS	CONDITION	IAGGRAVATED		Č Č	
	VIS	SION DISORI	DERS			LACRIMATI	ON ABNORMAL		u	
	ВО	DY AS A WI	HOLE - GENE	RAL DISORDE	ERS	EFFICACY,	LACK OF		t.	
	ACETAM	IINOPHEN				Concomitant			Ε Ε Γ	
	PROZAC					Concomitant				
	RIVOTRI	iL		. V		Concomitant	0.5 Milligrams		 0	
	XANAX					Concomitant	As necessary		F	

All Reports received and entered into database before April 12, 1999

Case report	Drug Age S	Sex Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
116387	ALLEGRA System Organ Class: RESPIRATORY SYS	male TEM DISORDERS E - GENERAL DISORDI	ERS	Suspected WHO Adverse RHINITIS EFFICACY,	e Reaction Term: LACK OF	Unknown
116388	ALLEGRA System Organ Class: VISION DISORDER:	E - GENERAL DISORDI	Continuing on Drug			Not yet recovered
0116389	ALLEGRA System Organ Class: RESPIRATORY SYS	emale STEM DISORDERS E - GENERAL DISORD	Continu ing on Drug ERS	Suspected WHO Advers SNEEZING EFFICACY, Other		Not yet recovered
0116394	ALLEGRA System Organ Class:	emale E - GENERAL DISORD	ERS	Suspected WHO Advers EFFICACY,	se Reaction Term: LACK OF	Unknown
0116399	30 Year(s) ALLEGRA System Organ Class: BODY AS A WHOL VISION DISORDER VISION DISORDER RESPIRATORY SY	E - GENERAL DISORD IS IS	3 Day(s) DERS	EFFICACY, EYE IRRITA		Not yet recovered

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April 12, 1999

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All Reports received and entered into database before April 12, 1999

O R 0116402	ALLEGRA System BODY RESP VISIC RESP CLARITIN REACTINE	IRATORY S ON DISORD	IOLE - GENEI SYSTEM DIS		Continuing on Drug	EFFICACY,	120 Milligrams Daily e Reaction Term:	Not yet recovered	
C R 0116402	System BODY RESP VISIC RESP CLARITIN REACTINE	Y AS A WHO IRATORY S ON DISORD	IOLE - GENEI SYSTEM DIS DERS	SORDERS	•	WHO Adverse EFFICACY, I	e Reaction Term:		
0116402	BODY RESP VISIC RESP CLARITIN REACTINE	Y AS A WHO IRATORY S ON DISORD	IOLE - GENEI SYSTEM DIS DERS	SORDERS	RS	EFFICACY,			
0116402	RESP VISIC RESP CLARITIN REACTINE	IRATORY S ON DISORD	SYSTEM DIS DERS	SORDERS	RS				
0116402	VISIO RESP CLARITIN REACTINE	ON DISORD	DERS				LACK OF		
0116402	RESP CLARITIN REACTINE			ORDERS		RHINITIS			
0116402	CLARITIN REACTINE	IRATORY .	SYSTEM DIS	CORDERS		EYE JRRITA			
0116402	REACTINE					SNEEZING E	EXCESSIVE		
0116402						Other			•
						Other			
A		Year(s)	Female					Not yet recovered	
	ALLEGRA				2 Day(s)	Suspected	120 Milligrams Daily		
		n Organ Cla					e Reaction Term:		
				RAL DISORDE	RS	EFFICACY,	LACK OF		
-			SYSTEM DIS	ORDERS		RHINITIS	0.05 MHP D.H.		
S	SYNTHROI)				Concomitant	0.75 Milligrams Daily		
0116405	-		Female					Recovered without sequelae	
A	ALLEGRA				! Week(s)	Suspected	60 Milligrams Daily		Σ
_		n Organ Cla					e Reaction Term:	Case and	. · (822PM
e de la medica de la composición de la La composición de la				RAL DISORDE	RS	EFFICACY,	LACK OF		
	RESP	RATORY	system dis	ORDERS		RHINITIS		.:	, 21
0116406			Male					Recovered without sequelac	
Α	ALLEGRA					Suspected	First dose		APR.13.
		n Organ Cla					e Reaction Term:		<u>R</u>
			SYSTEM DIS				G DIFFICULT		α
				M DISORDERS		TACHYCAR	DIA		1.1
		RATORY!	SYSTEM DIS	ORDERS		WHEEZES			TIME
O	OXYGEN	•				Treatment			
1	1								RECEIVED
lik E	ík.								\mathcal{A}_{i}
ų.	¥.								1.11

Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine All Reports received and entered into database before April 12, 1999

Case report	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0116655	R	ystem Organ C ESPIRATORY	y syst <mark>em</mark> dis	SORDERS M DISORDERS	i Mouth(s)	DYSPNOEA	60 Milligrams 2 Daily Reaction Term:	Recovered with sequelae	
	ORNAD PROCA	ODY AS A W		RAL DISORDE	RS	CHEST PAIN Concomitant Treatment Treatment			
0116768	ALLEG	RA	Female	<u> </u>	1 Week(s)	Suspecied WWG Advance	60 Milligrams Daily Reuction Term:	Recovered without sequelae	;
	R	ODY AS A W	Y SYSTEM DI	SORDERS ERAL DISORDE	RS	RHINITIS	ACK OF		
0116908		ystem Organ C		RAL DISORDE	3 Day(s)		Reaction Term: ACK OF	Not yet recovered	12:02PM
0116982	ESTRO MOTRI	System Organ (BODY AS A W GENS (ORAL	/HOLE - GENE -)	ERAL DISORDE	4 Day(s)		60 Milligrams Daily Reaction Term: ACK OF 0.625 Milligrams	Not yet recovered	TIME APR.13.
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All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
117437		36 Year(s)	Male					Unknown
	ALLEGR	RA .			Continuing on Drug	Suspected	120 Milligrams Daily	
	Sy.	stem Organ Cl	ass:			WHO Advers	e Reaction Term:	
	BC	DDY AS A WI	IOLE - GENEI	RAL DISORDEI	RS	SWELLING	NON-INFLAMMATORY	,
		(IN AND APP				HIVES		
	ВС	DDY AS A WI	IOLE - GENEI	RAL DISORDE	RS	EFFICACY,	LACK OF	
117596		27 Year(s)	Female					Not yet recovered
	ALLEGR	RA .			Continuing on Drug	Suspected	120 Milligrams	
		stem Organ Cl					e Reaction Term:	
		ESPIRATORY				SNEEZING I		
	BC	DDY AS A WI	IOLE - GENEI	RAL DISORDEI	RS	EFFICACY,	LACK OF	
117602		-	Male		- Ag- max	· · · · · · · · · · · · · · · · · · ·		Unknown
	ALLEGR	RA				Suspected		
		stem Organ Cl					e Reaction Term:	
	BC	DDY AS A WH	IOLE - GENEI	RAL DISORDEI	RS	EFFICACY,	LACK OF	
117627		30 Year(s)	Female			···		Recovered without sequelac
	ALLEGR	RA.			2 Day(s)	Suspected		
روال ليفحند الم		stem Organ Cl		ngo e n es ye e		The state of the s	e Reaction Term:	
	BC			RAL DISORDE		CHEST DISC		• .*
				RAL DISORDE	RS	HOT FLUSH		<i>.:</i>
			ND RHYTHM	1 DISORDERS		PALPITATIO	N	
	DOXYC	YCLINE				Concomitant		
117633		31 Year(s)	Female					Unknown
	ALLEGR	RA			Continuing on Drug	Suspected	60 Milligrams Daily	
		stem Organ Cl					e Reaction Term:	
				RAL DISORDE	RS	EFFICACY,		
	RESPIRATORY SYSTEM DISORDERS					NASAL CON		
	_1. VI	ISION DISORI	DERS			LACRIMAT	ION ABNORMAL	
	- M							^
								

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All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0117690		34 Year(s)	Male					Recovered without sequel	lac
	ALLEGR	A				Suspected	60 Milligrams		
		stem Organ Cl					e Reaction Term:		
	HI	eart rate a	ND RHYTHM	1 DISORDERS		PULSE IRRI	EGULARITY NOS		
0117730		33 Year(s)	Female					Not yet recovered	
0137700	ALLEGR	• •			Continuing on Drug	Suspected	120 Milligrams Daily		
		stem Organ Cla	ass:			WHO Advers	se Reaction Term:		
	-	SPIRATORY		ORDERS		RHINORRH	OEA		
	ВС	DDY AS A WH	IOLE - GENE	RAL DISORDE	RS	EFFICACY,	LACK OF		
	ACETAN	IINOPHEN W	VITH CODE	N	Continuing on Drug	Concomitant			
	CODEIN	E				Concomitant			
	DIMETA					Other			
0117743		23 Year(s)	Female		· ·			Not yet recovered	
	ALLEGE	:A			5 Day(s)	Suspected	60 Milligrams 2 Daily		
	Sy	stem Organ Cle	ass;			WHO Advers	e Reaction Term:		
	SK	IN AND APP	ENDAGES DI	SORDERS		ITCHING			
	В	DDY AS A WE	IOLE - GENE	RAL DISORDE	RS	EFFICACY,	LACK OF		
	-	SION DISORE				RED EYE			ģ
in the second	BO	DDY AS A WE	IOLE GENE	RAL DISORDE	RS ·	PAIN	the state of the state of	e e e e e e e e e e e e e e e e e e e	
	ACTIFE	D				Other			6
0117819		34 Year(s)	Malc					Not yet recovered	
	ALLEGE				3 Day(s)	Suspected	60 Milligrams 2 Daily		
		stem Organ Cl					se Reaction Term:		Ę
		ESPIRATORY		ORDERS			EXCESSIVE		7
		ISION DISORI					TON ABNORMAL		
		ESPIRATORY				RHINORRH			Į. Ž
	В	DDY AS A WE	HOLE - GENE	RAL DISORDE	RS	EFFICACY,	LACK OF		<u>Γ</u> Σ F
0117840	14	13 Усвг(s)	Male					Not yet recovered	
	ALLEGI					Suspected	1 2 Daily		, 1.
		stem Organ Cl			n.a		re Reaction Term:		
	В	DDY AS A WI	HOLE - GENE	RAL DISORDE	RS	EFFICACY,	LACK OF		Ö

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Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0117841		15 Year(s)	Male					Not yet recovered	
	ALLEGRA					Suspected	1 2 Daily		
	Syste	ın Organ Cle	255.			WHO Advers	e Reaction Term:		
	BOD	Y AS A WE	IOLE - GENE	RAL DISORDEI	RS	EFFICACY,	LACK OF		
117842		28 Year(s)	Female					Not yet recovered	
	ALLEGRA				Continuing on Drug	Suspected	2		
	Syste	m Organ Cle	255 :			WHO Advers	e Reaction Term;		
	BOD	Y AS A WE	IOLE - GENE	RAL DISORDEI	RS	EFFICACY,	LACK OF		
118121		18 Year(s)	Male					Not yet recovered	
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams 2 Daily		
	Syste	an Organ Cla	uss:			WHO Advers	e Reaction Term:		
	BOD	Y AS A WE	IOLE - GENE	RAL DISORDEI	RS	EFFICACY,	LACK OF		
118237		46 Year(s)	Mølc						
	ALLEGRA					Suspected			
•		m Organ Cle					e Reaction Term:		
		ON DISORI					IVAL CONGESTION		
	BOD	Y AS A WE	IOLE - GENE	RAL DISORDE	RS	EFFICACY,	LACK OF		Ž
118263	* 7 .4 . •		Female	Att.	9 C		1.	Uŋknown	
	ALLEGRA				~1 Week(s)	Suspected			0
		em Organ Cla					e Reaction Term:	•	
	BOD	Y AS A WE	IOLE - GENE	RAL DISORDE	RS	EFFICACY,	LACK OF		<u>,</u>
118331		35 Year(s)	Female					Recovered without sequelae	
	ALLEGRA					Suspected	60 Milligrams First dose		Ç
		em Organ Cle					e Reaction Term:		
			SYSTEM DIS			DYSPNOEA			L
				RAL DISORDE	28	CHEST PAIN		Ε Σ Ι-	
	HEA	RT RATE A	ND RHYTH	A DISORDERS		PALPITATIO	ON		
	4							- <u> </u>	
	•								Ĺ

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APR 13

Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofena dine

All Reports received and entered into database	before A	April	12 199	9
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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug
0118332	ALLEGI	38 Year(s) RA Istem Organ Cl	Female		~10 Day(s)	Suspected WHO Achiers	60 Milligrams 2 Da
	ŘÍ V	ESPIRATORY ISION DISORI	SYSTEM DIS		RS	RHINITIS	IVAL CONGESTIC
0118333		istem Organ Cl	Female ass: HOLE - GENER	RAL DISORDE	~1 Month(s)	Suspected WHO Advers EFFICACY,	120 Milligrams Di e Reaction Term: LACK OF
0118356		stem Organ Cl	Female ass: AND RHYTHM	I DISORDERS	l Day(s)	Suspected WHO Advers TACHYCAR	60 Milligrams 2 Di e Reaction Term: DIA
0118407		stem Organ Cl	Female lass: HOLE - GENEI	RAL DISORDE	5 Day(s)	Suspected WHO Advers EFFICACY,	60 Milligrams 2 Da e Reaction Term LACK OF
0118409	, B	ostem Organ Cl ODY AS A WI	Female lass: HOLE - GENEI SYSTEM DIS		Continuing on Drug	Suspected WHO Advers EFFICACY, SNEEZING	
0118440	B ந் G	ystem Organ Cl ODY AS A WI ASTRO-INTE	Pemale lass: HOLE - GENE STINAL SYST PH NERVOUS	EM DISORDE	RS		e Reaction Term: I OF WARMTH

2 Daily		Unknown	
TION			
Daily		Unknown	
2 Daily			
Daily		Not yet recovered	
·			12:02PM
Daily		Unknown	12.
<i>:</i>			APR.13.
		Unknown	
<i>:</i>			E I L
	· ·		

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Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
118538		72 Year(s)	Female					Recovered without sequelac
	ALLEGR					Suspected	60 Milligrams First dose	
		stem Organ Cl					e Reaction Term:	
			PH NERVOUS	SYSTEM DISC	ORDERS	CONVULSIO	ONS	
	METAM					Concomitant		
	SYNTHR	OID				Concomitant	0.25 Milligrams	
		28 Year(s)	Female					Recovered without sequelse
	ALLEGR	A			6 Week(s)	Suspected	120 Milligrams Daily	
	Sys	stem Organ Cl	ass:			WHO Advers		
				SYSTEM DISC	ORDERS	CONVULSION	SNC	
	LAMISIL	,			Continuing on Drug	Concomitant		
	MARVEI	.ON			Continuing on Drug	Concomitant		
	SOFRAC	ORT			Continuing on Drug	Concomitant		
	DILANTI	N				Treatment	100 Milligrams 3 Daily	
118604		13 Year(s)	Male				·	
	ALLEGR	A			3 Day(s)	Suspected	120 Milligrams Daily	
	Sys	item Organ Cl	ass:			WHO Advers		
	ВС	DY AS A WI	HOLE - GENE	RAL DISORDE	RS	EFFICACY,	LACK OF	
118607		13 Year(s)	Male					
	ALLEGR	A			2 Week(s)	Suspected	120 Milligrams Daily	·
	.Sy:	stem Organ Cl	ass:			WHO Advers	e Reaction Term:	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY,	LACK OF	

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Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome			
0118734		-	Pernale					Recovered without sequelae			
	ALLEGR	A				Suspected	I Dosage form First dose				
	Sy:	stem Organ C	lass:			WHO Advers	e Reaction Term:				
	CE	INTR & PERI	PH NERVOUS	SYSTEM DIS	ORDERS	DIZZINESS					
	VI	SION DISOR	DERS			VISION DOL	JBLE				
	CE	NTR & PERI	PH NERVOUS	SYSTEM DISC	ORDERS	WALKING D	DIFFICULTY				
	BETA-BI	OCKING A	GENTS			Suspected					
	Sys	stem Organ C	lass:			WHO Adverse	e Reaction Term:				
	CE	NTR & PERI	PH NERVOUS	SYSTEM DIS	ORDERS	DIZZINESS					
	CE	NTR & PERI	PH NERVOUS	SYSTEM.DISC	ORDERS	WALKING D	DIFFICULTY				
	VI	SION DISOR	DERS			VISION DOL	JBLE				
	CODEIN					Suspected					
		stem Organ C					e Reaction Term:				
		SION DISOR				VISION DOU	JBLE				
			PH NERVOUS			DIZZINESS					
			PH NERVOUS	SYSTEM DISC	ORDERS	WALKING D	DIFFICULTY				
	VALIUM					Suspected					
		stem Organ C				WHO Adverse					
			PH NERVOUS	SYSTEM DISC	ORDERS	DIZZINESS		•			
		SION DISOR				VISION DOL					
	CE	INTR & PERI	PH NERVOUS	SYSTEM DISC	ORDERS	WALKING D	DIFFICULTY	•	•		
0118757		-	Female								
	ALLEGR				6 Day(s)	Suspected					
		stem Organ C				WHO Adverse					
		SION DISOR				CONJUNCTIVAL CONGESTION					
			HOLE - GENER		RS	EFFICACY, I					
	RE	SPIRATORY	SYSTEM DISC	ORDERS		RHINITIS					
0118816		-	Male					Unknown			
	ALLEGR	Α			3-4 Day(s)	Suspected	60 Milligrams 2 Daily				
	i i	stem Organ C	lass:			WHO Adverse	Reaction Term:				
			HOLE - GENER	AL DISORDE	ERS	EFFICACY, I					
			SYSTEM DISC			SNEEZING E					

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Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine

All Reports received and entered into database before April 12, 1999

Case report number	Drug A	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
0118856	ALLEGRA System RESPIR BODY RESPIR VISION	AS A WH RATORY N DISORE N DISORE	SYSTEM DIS HOLE - GENE SYSTEM DIS DERS DERS	ERAL DISORDE	Continuing on Drug	RHINORRHO EFFICACY, THROAT IR EYE IRRITA	LACK OF RITATION	Not yet recovered	
0118857	ALLEGRA System RESPIR RESPIR	<i>Organ Cla</i> RATORY RATORY	Male ass: SYSTEM DIS SYSTEM DIS		40 Day(s)	Suspected	EXCESSIVE	Not yet recovered	
0118858	ALLEGRA System RESPIR	AS A WH	SYSTEM DIS	SORDERS - MINE		Suspected WHO Adverse RHINITIS EFFICACY, Concomitant Concomitant Concomitant	120 Milligrams Daily re Reaction Term: LACK OF	e anno 120 de seu la	. 13. 12:82PM
0119143	ALLEGRA System VISION RESPIR		DERS SYSTEM DI	ISORDERS ERAL DISORDE	3 Day(s) ERS	Suspected WHO Adverse CONJUNCT: RHINITIS EFFICACY,		-	RECEIVED TIME APR

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All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
D119164	R	ystem Organ Cl ESPIRATORY	SYSTEM DIS	ORDERS RAL DISORDE	Continuing on Drug	Suspected WHO Advers SNEEZING I EFFICACY,		Not yet recovered	
0119231	ALLEG S V B	27 Year(s) RA ystem Organ Cl ISION DISORI	Male lass: DERS HOLE - GENEI	RAL DISORDE	Continuing on Drug	Suspected WHO Advers	60 Milligrams 2 Daily e Reaction Term: ION ABNORMAL LACK OF	Not yet recovered	
0119232	R	ystem Organ Cl ESPIRATORY ISION DISORI	' SYSTEM DIS DERS	ORDERS RAL DISORDE	Continuing on Drug	Suspected WHO Advers NASAL CON EYE IRRITA EFFICACY,	TION	Not yet recovered	
0119260	R	ystem Organ Cl ESPIRATORY	SYSTEM DIS	SORDERS RAL DISORDE	Continuing on Drug	Suspected WHO Advers NASAL CON EFFICACY,		Not yet recovered	•
0119329	B	ystem Organ Cl	HOLE - GENE PENDAGES DI		Continuing on Drug	Suspected WHO Advers EFFICACY, ITCHING NASAL CON		Not yet recovered	

All Reports received and entered into database before April 12, 1999

Case report	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug		
0119330		37 Year(s)	Female						
	ALLEGR				9 Day(s)	Suspected	60 Milligrams 2 Da		
		stem Organ Cl					e Reaction Term:		
			SYSTEM DIS				EXCESSIVE		
				RAL DISORDE	ERS	EFFICACY,	LACK OF		
	_		ENDAGES DI			ITCHING			
	RE	ESPIRATORY	SYSTEM DIS	ORDERS		NASAL CO	NGESTION		
	PREMAR	RIN				Concomitant			
	CLARITI	IN				Other			
	SELDAN	E				Other			
0119331		59 Year(s)	Male						
	ALLEGR				4-5 Day(s)	Suspected	60 Milligrams 2 Da		
		siem Organ Cl					se Reaction Term:		
			SYSTEM DIS				EXCESSIVE		
	BC	DY AS A WI	HOLE - GENE	RAL DISORDE	ERS	EFFICACY,			
•	SE	CONDARY T	TERMS			EYE BURNS			
	VITAMI	N C				Concomitant			
	VITAMI	Y E				Concomitant			
	REACTI	NE				Other	# who		
0119332		27 Year(s)	Female						
	ALLEGR	l A			6-7 Day(s)	Suspected	60 Milligrams 2 Da		
	Sy.	stem Organ Cl	lass:			WHO Adverse Reaction Term:			
	RE	ESPIRATORY	SYSTEM DIS	ORDERS		RHINORRH			
	ВС	DDY AS A WI	HOLE - GENE	RAL DISORDE	ERS	EFFICACY,	LACK OF		
0119333		38 Year(s)	Female						
	ALLEGR				Continuing on Drug	Suspected	60 Milligrams 2 Di		
		stem Organ C				WHO Adverse Reaction Term:			
			SYSTEM DIS	SORDERS		RHINORRHOEA			
	VISION DISORDERS PODY AS A WHOLE GENERAL DISORDERS					LACRIMATION ABNORMAL			
	₩ BC	DDY AS A W	HOLE - GENE	RAL DISORDE	ERS	EFFICACY,	LACK OF		

Outcome

Not yet recovered

Not yet recovered

Not yet recovered

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Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
119440		44 Yenr(8)	Female					Not yet recovered	
	ALLEGI	RA			10 Day(s)	Suspected	60 Milligrams 2 Daily		
		stem Organ C					e Reaction Term:		
			SYSTEM DIS	ORDERS		RHINITIS			
		ISION DISOR				CONJUNCT			
			SYSTEM DIS			SNEEZING			
	В	ODY AS A WI	HOLE - GENE	RAL DISORDE	SK2	EFFICACY,	LACK OF		
119484		24 Year(s)	Male					Not yet recovered	
	ALLEGI	RA			2 Day(s)	Suspected	60 Milligrams 2 Daily		
		istem Organ Ci					e Reaction Term:		
				RAL DISORDE	CRS	EFFICACY,			
	R	ESPIRATORY	SYSTEM DIS	ORDERS		SNEEZING	EXCESSIVE		
	SELDAN	1E				Other			
119710		29 Year(s)	Female					Not yet recovered	
	ALLEGI	RA			Continuing on Drug	Suspected	60 Milligrams Daily		
		stem Organ C					e Reaction Term:		
			SYSTEM DIS			SNEEZING I			
	B	ody as a wi	HOLE - GENE	RAL DISORDE	ERS	EFFICACY,	LACK OF		
119711		42 Year(s)	Female					Not yet recovered	•
	ALLEGI	RA			~1 Month(s)	Suspected	60 Milligrams Daily	.2	
	S	stem Organ C	lass:			WHO Advers			
	В	ODY AS A W	HOLE - GENE	RAL DISORDE	ERS	EFFICACY,			
	INHALE	R THERAPY	•			Concomitant			
	CLARIT	'NI'				Other			
120001		36 Year(s)	Male					Died drug may be contributory	
1120001	ALLEG		Marc			Suspected	60 Milligrams First dose		
		NA ystem Organ C	lass.			WHO Advers	e Reaction Term:		
				EM DISORDE	RS	GAGGING			
			SYSTEM DIS		- ··-	COUGHING	ł		
	A	JJI MATONI							

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Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine

All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome		
0120002		28 Year(s)	Female					Recovered without soquelae		
	ALLEGR	. A ·			-4 Day(s)	Suspected	60 Milligrams 2 Daily			
	Sys	stem Organ C	lass:			WHO Advers	se Reaction Term:			
				RAL DISORDE	RS	EFFICACY,	LACK OF			
0122329		57 Year(s)	Male					Recovered with sequelae		
V	ALLEGR	A			~2 Month(s)	Suspected	120 Milligrams Daily	-		
	Sys	stem Organ C	lass:			WHO Advers	se Reaction Term:			
	BC	DY AS A W	HOLE - GENEI	RAL DISORDE	RS	CHEST TIG	HTNESS OF			
	HE	EART RATE	AND RHYTHM	1 DISORDERS		ATRIAL FIE	BRILLATION PAROXY	SMAL		
	H	EART RATE	AND RHYTHM	1 DISORDERS		PULSE RAT	E INCREASED			
	RE	SPIRATORY	SYSTEM DIS	ORDERS		BREATH SE	HORTNESS			
	ORNADE	;				Concomitant				
	PROCAI					Treatment	30 Milligrams			
	VERAPA	MIL				Tresinient	5 Milligrams			
0122494		21 Year(s)	Female		· · · · · · · · · · · · · · · · · · ·			Recovered without sequelac		
	ALLEGR				3-4 Day(s)	Suspected	240 Milligrams Daily			
		stem Organ C				WHO Adverse Reaction Term:				
				EM DISORDE		MUSCLE PAIN				
	BC	DDY AS A W	HOLE - GENEI	RAL DISORDE	RS	THORACIC	PAIN	77 4.5 2 1 ° 77 644.		
0122508		61 Year(s)	Male					Recovered without sequelac		
	ALLEGR					Suspected	60 Milligrams 2 Daily			
		stem Organ C				WHO Adverse Reaction Term:				
				M DISORDERS			E INCREASED			
	*			M DISORDERS		PALPITATI				
		N HYDROCI	HLORIDE			Concomitant	50 Milligrams Daily			
	DURALI					Concomitant	300 Milligrams 2 Daily			
	FLUOXE					Concomitant	20 Milligrams Daily			
	CEMFIB	ROZIL		ş] .		Concomitant	600 Milligrams 2 Daily			
	MODUL					Concomitant	100 Milligrams 3 Daily			
	PERCOC	ET				Concomitant	1 Dosage form 4 Daily			

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Canadian Adverse Drug Reaction Monitoring Program Summary of Reported Adverse Drug Reactions Active Ingredient: Fexofenadine

All Reports received and entered into database before April 12, 1999

Case report	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome	
					 				

Total No. of reports 79

Total No. of reports with fatal outcome 1

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